



07-12-06

IFW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/786,997	Conf. No. 9030
	Filing Date	February 24, 2004	
	First Named Inventor	Roger D. Tung, et al.	
	Art Unit	1621	
	Examiner Name	Elvis O. Price	
Total Number of Pages in This Submission	18	Attorney Docket Number	VPI/92-07 CIP2A DIV3 CON

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 <input type="checkbox"/> Copy of Notice of file Missing Parts of Nonprovisional Application	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): -- Petition for Withdrawal of Holding of Abandonment with Exhibits A-I; and -- Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Fish & Neave IP Group Ropes & Gray LLP		
	Customer No. 1473		
Signature			
Printed name	Karen Mangasarian		
Date	July 10, 2006	Reg. No.	43,772

EXPRESS MAIL CERTIFICATION			
I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to Mail Stop Missing Parts, Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			
Signature			
Typed or printed name	Andrew Shive	Date	July 10, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Express Mail Label
No. EV669673351US

PATENTS
Attorney Docket No. VPI92-07CIP2ADIV3CON



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Applicants : Roger D. Tung, et al.
Application No. : 10/786,997 Confirmation No. : 9030
Filed : February 24, 2004
For : NOVEL SULFONAMIDE INHIBITORS OF
ASPARTYL PROTEASE
Group Art Unit : 1621
Examiner : Elvis O. Price

New York, New York 10020
July 10, 2006

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PETITION FOR WITHDRAWAL OF HOLDING OF ABANDONMENT

Sir:

Applicants hereby petition under 37 C.F.R. § 1.181 to withdraw the holding of abandonment set forth in the Notice of Abandonment mailed on June 26, 2006 (copy attached at Exhibit A). In accordance with 37 C.F.R. § 1.181(f), applicants make this Petition within two months of the mailing date of the Notice of Abandonment.

The Notice of Abandonment states that the application is abandoned for failure to respond to the Office Action mailed on December 20, 2005 (copy attached as Exhibit B).

On June 20, 2006, applicants filed, by United States Postal Service Express Mail (Express Mail Label No. EV674902255US) an Amendment and Reply (copy attached as Exhibit C), which was accompanied by a Transmittal Letter having an Express Mail Certification (copy attached as Exhibit D), a petition for a three-month extension of time authorized the Director to charge payment of the appropriate fee to the deposit account 06-1075 (copy attached as Exhibit E) and a return postcard (copy attached a Exhibit F). These papers all indicated Express Mail Label No. EV674902255US. A copy of the Express Mail Label bearing Express Mail Label No. EV674902255US is attached as Exhibit G.

The Express Mail Certification (see Exhibit D) demonstrates that the Amendment and Reply, was timely filed. See 37 C.F.R. § 1.10 and MPEP § 711.03(c)(I)(B). Moreover, the USPTO Public PAIR system indicates that an Amendment and Reply was filed on June 20, 2006 (printout of the Public PAIR Image File Wrapper for this application attached at Exhibit H). A printout of the imaged documents from Public PAIR contains a June 20, 2006 date-stamp by the Patent and Trademark Office, evidencing receipt of applicants' Amendment and Reply to Office Action and accompanying Petition for Extension of Time and Transmittal Letter (copy attached as Exhibit I).

Applicants respectfully submit that the Notice of Abandonment was issued in error because applicants timely filed an Amendment and Reply on June 20, 2006. Applicants respectfully request that the holding of abandonment be withdrawn.

Applicants believe that no fees are due in connection with this Petition. However, the Director is hereby authorized to charge payment of any fee that may be required in connection with the Petition to Deposit Account No. 06 1075, Order No. (Account No. 003667-0048). A duplicate copy of this Petition is enclosed herewith.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)
Karen Mangasarian (Reg. No. 43,772)
Attorneys for Applicants

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
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New York, New York 10020-1105
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Fax: (212) 596-9090



Express Mail Label
No. EV669673351US

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Attorney Docket No. VPI92-07CIP2ADIV3CON

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PATENT APPLICATION

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Respectfully submitted,



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Karen Mangasarian (Reg. No. 43,772)
Attorneys for Applicants

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,997

02/24/2004

Roger D. Tung

VPI9207C2AD3

9030

1473

7590

06/26/2006

FISH & NEAVE IP GROUP

ROPES & GRAY LLP

1251 AVENUE OF THE AMERICAS FL C3

NEW YORK, NY 10020-1105

RECEIVED

JUN 29 2006

ROPES & GRAY LLP, PATENT DEPT.
REFERRED TO RM
NOTED BY RM

EXAMINER

PRICE, ELVIS O

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

File No.: VPI/96-07C1P2A
Action Desc: Abandon?
Due Date: 8-26-06
By LS

Notice of Abandonment

Application No.

10/786,997

Examiner

Elvis O. Price

Applicant(s)

TUNG ET AL.

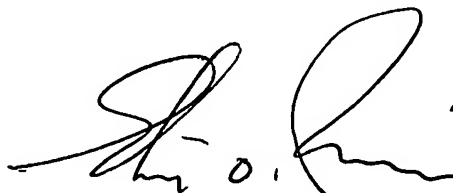
Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 20 December 2005.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:



Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,997	02/24/2004	Roger D. Tung	VP19207C2AD3	9030

1473 7590 12/20/2005

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

RECEIVED

DEC 23 2005

DATE MAILED: 12/20/2005

ROPES & GRAY LLP - PATENT DEPT.
REFERRED TO K21
NOTED BY _____

EXAMINER	
PRICE, ELVIS O	
ART UNIT	PAPER NUMBER
1621	

Please find below and/or attached an Office communication concerning this application or proceeding.

**COPY SENT TO VERTEX
VIA POUCH MAIL**

DOCKETED FOR

3/20/2006
3 Month Office Action

Office Action Summary

Application No.

10/786,997

Applicant(s)

TUNG ET AL

Examiner

Elvis O. Price

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 11, 12 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/12/05.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 10/26/05.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1621

DETAILED ACTION

Claims 1-5, 7, 11, 12, 16-24 are pending in the application.

Election/Restrictions

Applicant's election, with traverse, of Group VIII in the reply filed on 12/21/04 is acknowledged. The traversal is on the ground(s) that it would not be burdensome to the Examiner to search all groups because a search for all groups can be carried out simultaneously. This is not found persuasive because prior art anticipating or rendering obvious any one group of invention would not necessarily anticipate or render obvious the inventions of other groups. Thus, it would be burdensome for the Examiner to search and prosecute all groups of inventions. Claims 16-24 still remain withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

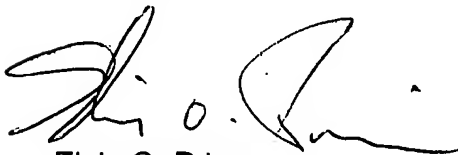
Claims 1-5, 7, 11 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 5 contain subject matter which was not elected. The language of claims 1 and 5 defines a "Het" group related to the variable "A", however, the variable "A", as defined by the elected subject matter of Group VIII, should not contain a "Het" group. Appropriate correction is required.

Art Unit: 1621

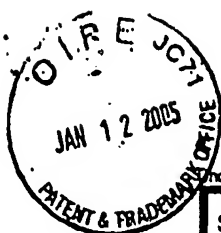
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elvis O. Price whose telephone number is 571 272-0644. The examiner can normally be reached on 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Elvis O. Price', with a stylized flourish at the end.

Elvis O. Price



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 5		Complete if known	
		Application Number	10/786,997
		Filing Date	February 24, 2004
		First Named Inventor	Roger D. Tung et al.
		Art Unit	1625
		Examiner Name	D. Margaret Seaman
		Attorney Docket Number	VPI/92-07CIP2ADIV3 CON

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 3,743,722	07/03/1973	Mohrs et al.	
		US- 4,330,542	05/18/1982	Descamps et al.	
		US- 4,629,724	12/16/1986	Ryono et al.	
		US- 5,196,438	03/23/1993	Martin et al.	
		US- 5,354,866	10/11/1994	Kempf et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		EP-0 022 118	01/07/1981	Sanofi SA		
		EP-0 181 071	03/14/1986	Squibb & Sons, Inc.		
		EP-0 264 795	04/27/1988	Merck Patent GmbH		
		EP-0 346 847	12/20/1989	Hoffmann LaRoche		
		EP-0 364 804	04/ 25/1990	Abbott Laboratories		
		EP-0 468 641	01/29/1992	Shionogi & Co.		
		EP-0 486 948	05/27/1992	Abbott Laboratories		
		EP-0 541 168	05/12/1993	Merck & Co. Inc.		
		DE-3542567	06/05/1986	Squibb & Sons, Inc.		
		GB-2,167,759	6/04/1986	Squibb & Sons, Inc.		
		GB-2,200,115	07/27/1988	Sandoz Ltd.		
		JP-59046252	03/15/1984	Dainippon Ink & Chemicals; Dainippon Ink Rikagaku Kenkuis		
		JP-59048449	03/19/1984	Dainippon Ink & Chemicals; Dainippon Ink Rikagaku Kenkuis		

Examiner Signature		Date Considered	10/27/05
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.07 and 1.08. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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[illegible]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO				Complete if known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/786,997
				Filing Date	February 24, 2004
				First Named Inventor	Roger D. Tung et al.
				Art Unit	1625
				Examiner Name	D. Margaret Seaman
Sheet	3	of	5	Attorney Docket Number	VPI/92-07CIP2ADIV3 CON

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
JS		R.D. Bindal et al., "Ab Initio Calculations on N-Methylmethanesulfonamide and Methyl Methanesulfonate for the Development of Force Field Torsional Parameters and Their Use in the Conformational Analysis of Some Novel Estrogens", <i>J. Am. Chem. Soc.</i> , 112, pp. 7861-68 (1990).	
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		R.F. Borch et al., "The Cyanohydridoborate Anion as a Selective Reducing Agent", <i>J. Am. Chem. Soc.</i> , 93, pp. 2897-904 (1971).	
		J.C. Craig et al., "Antiviral Synergy Between Inhibitors of HIV Proteinase and Reverse Transcriptase", <i>Antiviral Chem. and Chemotherapy</i> , 4(3), pp. 161-66 (1990).	
		S. Crawford et al., "A Deletion Mutation in the 5' Part of the pol Gene of Moloney Murine Leukemia Virus Blocks Proteolytic Processing of the gag and pol Polyproteins", <i>J. Virol.</i> , 53, pp. 899-907 (1985).	
		M. Cushman et al., "Development of Methodology for the Synthesis of Stereochemically Pure Pheψ[CH ₂ N]Pro Linkages in HIV Protease Inhibitors", <i>J. Org. Chem.</i> , 56, pp. 4161-67 (1991).	
		D.S. Dhanoa et al., "The Synthesis of Potent Macrocyclic Renin Inhibitors", <i>Tetrahedron Lett.</i> , 33, pp. 1725-28 (1992).	
		G.B. Dreyer et al., "Hydroxyethylene Isostere Inhibitors of Human Immunodeficiency Virus-1 Protease: Structure-Activity Analysis Using Enzyme Kinetics, X-ray Crystallography, and Infected T-Cell Assays", <i>Biochemistry</i> , 31, pp. 6646-59 (1992).	
		B.E. Evans et al., "A Stereocontrolled Synthesis of Hydroxyethylene Dipeptide Isosteres Using Novel, Chiral Aminoalkyl Epoxides and γ-(Aminoalkyl) γ-Lactones", <i>J. Org. Chem.</i> , 50, pp. 4615-25 (1985).	
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		G. Fontenot et al., "PCR Amplification of HIV-1 Proteinase Sequences Directly from Lab Isolates Allows Determination of Five Conserved Domains", <i>Virology</i> , 190, pp. 1-10 (1992).	
		P.G. Gassman and T.L. Guggenheim, "Opening of Epoxides with Trimethylsilyl Cyanide to Produce β-Amino Alcohols", <i>J. Am. Chem. Soc.</i> , 104, pp. 5849-50 (1982).	
		E.E. Gilbert, "Recent Developments in Preparative Sulfonation and Sulfation", <i>Synthesis</i> , 1969, pp. 3-10 (1969).	
JS		A. Goldblum, "Modulation of the Affinity of Aspartic Proteases by the Mutated Residues in Active Site Models", <i>FEBS</i> , 261, pp. 241-44 (1990).	
		D. Grobelny et al., "Selective Phosphinate Transition-State Analogue Inhibitors of the Protease of Human Immunodeficiency Virus", <i>Biochem. Biophys. Res. Commun.</i> , 169, pp. 1111-16 (1990).	

Examiner Signature	<i>Shi o. Lu</i>	Date Considered	10/27/05
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.87 and 1.88. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO		Complete if known.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/786,997
		Filing Date	February 24, 2004
		First Named Inventor	Roger D. Tung et al.
		Art Unit	1625
		Examiner Name	D. Margaret Seaman
Sheet 4 of 5	Attorney Docket Number	VPI/92-07CIP2ADIV3 CON	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
J.S.		G.D. Hartman et al., "4-Substituted Thiophene- and Furan-2-sulfonamides as Topical Carbonic Anhydrase Inhibitors", <i>J. Med. Chem.</i> , 35, pp. 3822-31 (1992).	
		J.R. Huff, "HIV Protease: A Novel Chemotherapeutic Target for AIDS", <i>Journal of Medicinal Chemistry</i> , 34(8), pp. 2305-14 (1991).	
		K.Y. Hui et al., "A Rational Approach in the Search for Potent Inhibitors Against HIV Proteinase", <i>FASEB</i> , 5, pp. 2606-10 (1991).	
		N.E. Kohl et al., "Active HIV Protease is Required for Viral Infectivity", <i>Proc. Natl. Acad. Sci. USA</i> , 85, pp. 4686-90 (1988).	
		X. Lin et al., "Enzymic Activities of Two-Chain Pepsinogen, Two-Chain Pepsin, and the Amino-Terminal Lobe of Pepsinogen", <i>J. Biol. Chem.</i> , 267(24), pp. 17257-63 (1992).	
		K.P. Manfredi et al., "Examination of HIV-1 Protease Secondary Structure Specificity Using Conformationally Constrained Inhibitors", <i>J. Med. Chem.</i> , 34, pp. 3395-99 (1991).	
		F.R. Marshall, "Computer-Aided Drug Design", <i>Ann. Rev. Pharmacol. Toxicol.</i> , 27, pp. 193-213 (1987).	
		J.A. Martin, "Recent Advances in the Design of HIV Proteinase Inhibitors", <i>Antiviral Research</i> , 17, pp. 265-78 (1992).	
		T.D. Meek et al., "Inhibition of HIV-1 Protease in Infected T-Lymphocytes by Synthetic Peptide Analogues", <i>Nature</i> , 343, pp. 80-92 (1990).	
		M. Miller et al., "Structure of Complex of Synthetic HIV-1 Protease with a Substrate-Based Inhibitor at 2.3 Å Resolution", <i>Science</i> , 246, pp. 1149-52 (1989).	
		M. Miller et al., "Crystal Structure of a Retroviral Protease Proves Relationship to Aspartic Protease Family", <i>Nature</i> , 337, pp. 576-79 (1989).	
		H. Mitsuya and S. Broder, "Inhibition of the <i>in vitro</i> Infectivity and Cytopathic Effect of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus (HTLV-III/LAV) by 2',3'-Dideoxynucleosides", <i>Proc. Natl. Acad. Sci. USA</i> , 83, pp. 1911-15 (1986).	
		K.H.M. Murthy et al., "Crystal Structures at 2.2-Å Resolution of Hydroxyethylene-Based Inhibitors Bound to Human Immunodeficiency Virus Type 1 Protease Show That the Inhibitors Are Present in Two Distinct Orientations", <i>J. Biol. Chem.</i> , 267, pp. 22770-78 (1992).	
		J.B. Nichols et al., "A Molecular Mechanics Valence Force Field for Sulfonamides Derived by <i>ab initio</i> Methods", <i>J. Phys. Chem.</i> , 95, pp. 9803-11 (1991).	
	J.S.		L.E. Overman and L.A. Flippin, "Facile Aminolysis of Epoxides with Diethylaluminum Amides", <i>Tetrahedron Letters</i> , 195, pp. 195-98 (1981).
		J. Palca, "Shooting at a New HIV Target", <i>Science</i> , 247, p. 410 (1990).	
		L.H. Pearl et al., "A Structural Model for the Retroviral Proteases", <i>Nature</i> , 329, pp. 329-51 (1987).	


Examiner Signature	<i>[Signature]</i>	Date Considered	10/27/05
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/786,997
				Filing Date	February 24, 2004
				First Named Inventor	Roger D. Tung et al.
				Art Unit	1625
				Examiner Name	D: Margaret Seaman
(use as many sheets as necessary)				Attorney Docket Number	VPI/92-07CIP2ADIV3 CON
Sheet	5	of	5		

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Examiner Signature		Date Considered	10/27/05
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PATENTS

Attorney Docket No. VPI92-07CIP2ADIV3CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Examiner : Elvis O. Price
Group Art Unit : 1621
Applicants : Roger D. Tung, et al.
Application No. : 10/786,997 Confirmation No. : 9030
Filed : February 24, 2004
For : NOVEL SULFONAMIDE INHIBITORS OF
ASPARTYL PROTEASE

New York, New York 10020
June 20, 2006

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

AMENDMENT AND REPLY TO OFFICE ACTION

Sir:

This is in response to the December 20, 2005 Office Action in the above-identified application. Applicants submit concurrently herewith a Petition under 37 C.F.R. § 1.17(a)(3) to extend the time for replying for a period of three months up to and including June 20, 2006.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

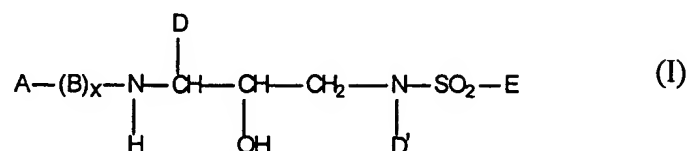
Remarks begin on page 12 of this paper.

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (previously presented): A compound of formula I:



wherein:

A is selected from the group consisting of $-\text{R}^1-\text{C}_1-\text{C}_6$ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C_1-C_4 alkoxy, $-\text{NR}^2-\text{CO}-\text{N}(\text{R}^2)(\text{R}^2)$ and $-\text{CO}-\text{N}(\text{R}^2)(\text{R}^2)$;

each R^1 is independently selected from the group consisting of $-\text{C}(\text{O})-$, $-\text{S}(\text{O})_2-$, $-\text{C}(\text{O})-\text{C}(\text{O})-$, $-\text{O}-\text{C}(\text{O})-$, $-\text{O}-\text{S}(\text{O})_2-$, $-\text{NR}^2-\text{S}(\text{O})_2-$, $-\text{NR}^2-\text{C}(\text{O})-$ and $-\text{NR}^2-\text{C}(\text{O})-\text{C}(\text{O})-$;

each Het is independently selected from the group consisting of C_3-C_7 cycloalkyl; C_5-C_7 cycloalkenyl; C_6-C_{10} aryl; and 5-7 membered saturated or unsaturated heterocycle, containing one heteroatom selected from N, $\text{N}(\text{R}^2)$, O, S and $\text{S}(\text{O})_n$, wherein said heterocycle may optionally be benzofused; and wherein any member of said Het

may be optionally substituted with one or more substituents selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)(R^2)$, $-R^2-OH$, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)(R^2)$, $-S(O)_2-N(R^2)(R^2)$, $-N(R^2)-C(O)-R_2$, $-C(O)-R^2$, $-S(O)_n-R^2$, $-OCF_3$, $-S(O)_n-Ar$, methylenedioxy, $-N(R^2)-S(O)_2(R^2)$, halo, $-CF_3$, $-NO_2$, Ar and $-O-Ar$;

each R^2 is independently selected from the group consisting of H and C_1 - C_3 alkyl optionally substituted with Ar; with the proviso that when R^2 is C_1 - C_3 alkyl substituted with Ar, said Ar may not be substituted with an Ar-containing moiety;

B, when present, is $-N(R^2)-C(R^3)(R^3)-C(O)-$;

x is 0 or 1;

each R^3 is independently selected from the group consisting of H, Het, C_1 - C_6 alkyl, C_2 - C_6 alkenyl, C_3 - C_6 cycloalkyl and C_5 - C_6 cycloalkenyl, wherein any member of said R^3 , except H, may be optionally substituted with one or more substituents selected from the group consisting of $-OR^2$, $-C(O)-NH-R^2$, $-S(O)_n-N(R^2)(R^2)$, Het, $-CN$, $-SR^2$, $-CO_2R^2$, $NR^2-C(O)-R^2$;

each n is independently 1 or 2;

D and D' are independently selected from the group consisting of Ar; C_1 - C_4 alkyl, which may be optionally substituted with one or more groups selected from C_3 - C_6 cycloalkyl, $-OR_2$, $-R^3$, $-O-Ar$ and Ar; C_2 - C_4 alkenyl, which may be optionally substituted with one or more groups selected from the group consisting of C_3 - C_6 cycloalkyl, $-OR^2$, $-R^3$, $-O-Ar$ and Ar; C_3 - C_6 cycloalkyl, which may be optionally substituted with or fused with Ar; and C_5 - C_6 cycloalkenyl, which may be optionally

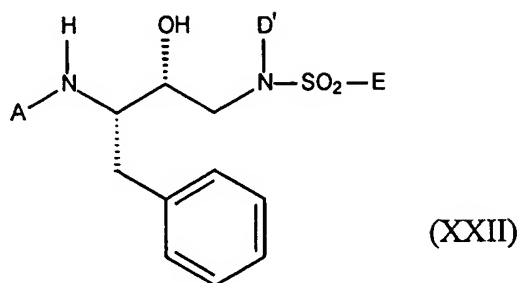
substituted with or fused with Ar;

each Ar is independently selected from the group consisting of phenyl; 3-6 membered carbocyclic ring, wherein said carbocyclic ring may be saturated or unsaturated and optionally substituted with one or more groups selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)(R^2)$, $-N(R^2)-C(O)-R^2$, C_1-C_3 alkyl substituted with -OH and optionally substituted with Ar, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)(R^2)$, halo and $-CF_3$;

E is selected from the group consisting of Het; O-Het; Het-Het; $-OR^3$; $-NR^2R^3$; C_1-C_6 alkyl, which may be optionally substituted with one or more groups selected from the group consisting of R^4 and Het; C_2-C_6 alkenyl, which may be optionally substituted with one or more groups selected from the group consisting of R^4 and Het; C_3-C_6 saturated carbocycle, which may optionally be substituted with one or more groups selected from the group consisting of R^4 and Het; and C_5-C_6 unsaturated carbocycle, which may optionally be substituted with one or more groups selected from the group consisting of R^4 and Het; and

each R^4 is independently selected from the group consisting of $-OR^2$, $-C(O)-NHR^2$, $-S(O)_2-NHR^2$, halo, $-NR^2-C(O)-R^2$ and $-CN$.

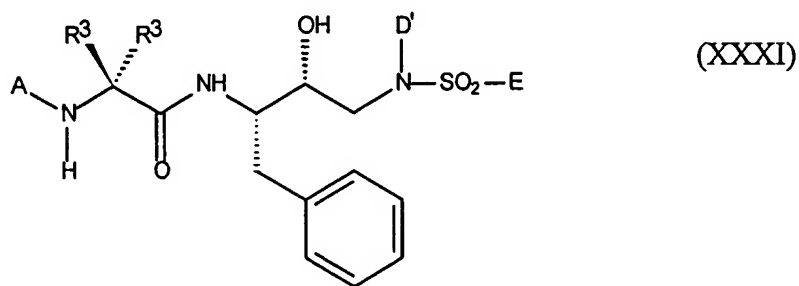
Claim 2 (original): The compound according to claim 1, characterized in that said compound has the structure of formula XXII:



and A, D' and E are defined as in claim 1.

Claim 3 (canceled).

Claim 4 (original): The compound according to claim 1, characterized in that said compound has the structure of formula XXXI:



and A, R³, D' and E are defined as in claim 1.

Claim 5 (previously presented): A compound of formula I, wherein:

A is selected from the group consisting of $-R^1-C_1-C_6$ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C_1-C_4 alkoxy;

each R^1 is independently selected from the group consisting of $-C(O)-$, $-S(O)_2-$, $-C(O)-C(O)-$, $-O-CO-$, $-O-S(O)_2-$ and $-NR^2-S(O)_2-$;

each Het is independently selected from the group consisting of C_3-C_7 cycloalkyl; C_5-C_7 cycloalkenyl; C_6-C_{10} aryl; and 5-7 membered saturated or unsaturated heterocycle, containing one heteroatom selected from N, O and S, which may optionally be benzofused; wherein any member of said Het may be optionally substituted with one or more substituents selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)_2$, $-R^2-OH$, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)_2$ and $-S(O)_2-N(R^2)_2$;

each R^2 is independently selected from the group consisting of H and C_1-C_3 alkyl;

B, when present, is $-NH-CH(R^3)-C(O)-$;

x is 0 or 1;

R^3 is selected from the group consisting of Het, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_3-C_6 cycloalkyl and C_5-C_6 cycloalkenyl, wherein any member of said R^3 may be optionally substituted with one or more substituents selected from the group consisting of $-OR^2$, $-C(O)-NH-R^2$, $-S(O)_n-N(R^2)_2$, Het and $-CN$;

n is 1 or 2;

D and D' are independently selected from the group consisting of Ar; C₁-C₄ alkyl, which may be optionally substituted with C₃-C₆ cycloalkyl or Ar; C₂-C₄ alkenyl, which may be optionally substituted with C₃-C₆ cycloalkyl or Ar; C₃-C₆ cycloalkyl, which may be optionally substituted or fused with Ar; and C₅-C₆ cycloalkenyl, which may be optionally substituted or fused with Ar;

Ar is selected from the group consisting of phenyl; 3-6 membered carbocyclic ring wherein said carbocyclic ring may be saturated or unsaturated and optionally substituted with one or more groups selected from the group consisting of oxo, -OR², -R², -N(R²)₂, -N(R²)-C(O)R², -R²-OH, -CN, -CO₂R², -C(O)-N(R²)₂, halo and -CF₃;

E is selected from the group consisting of Het; -O-R³; -NR²R⁵; C₁-C₆ alkyl, which may be optionally substituted with one or more R⁴ or Het; C₂-C₆ alkenyl, which may be optionally substituted with one or more R⁴ or Het; C₃-C₆ saturated carbocycle, which may optionally be substituted with one or more R⁴ or Het; and C₅-C₆ unsaturated carbocycle, which may optionally be substituted with one or more R⁴ or Het;

each R⁴ is independently selected from the group consisting of -OR², -C(O)-NHR², -S(O)₂-NHR², halo and -CN; and

each R⁵ is independently selected from the group consisting of H and R³.

Claim 6 (canceled).

Claim 7 (currently amended): The compound according to claim 1, wherein:

R³ is selected from the group consisting of C₁-C₆ alkyl, C₂-C₆ alkenyl, C₅-

C₆ cycloalkyl, C₅-C₆ cycloalkenyl and a 5-6 membered saturated or unsaturated heterocycle, wherein any member of said R³ may optionally be substituted with one or more substituents selected from the group consisting of -OR², -C(O)-NH-R², -S(O)_nN(R²)(R²), Het, -CN, -SR², -C(O)₂R², NR²-C(O)-R²; and

D' is selected from the group consisting of C₁-C₃ alkyl and C₃ alkenyl, wherein said alkyl or alkenyl may optionally be substituted with one or more groups selected from the group consisting of C₃-C₆ cycloalkyl, -OR², -O-Ar and Ar.

Claims 8-10 (canceled).

Claim 11 (original): The compound according to claim 1, wherein said compound has a molecular weight less than or equal to about 700 g/mol.

Claim 12 (currently amended): A The compound according to claim 11, wherein said compound has a molecular weight less than or equal to about 600 g/mol.

Claims 13-15 (canceled).

Claim 16 (withdrawn – currently amended): A pharmaceutical composition effective against viral infection comprising a pharmaceutically effective amount of a compound according to any one of claims 1-2 or 4 and a pharmaceutically acceptable carrier, adjuvant or vehicle.

Claim 17 (withdrawn): The pharmaceutical composition according to claim 16, further comprising an additional anti-viral agent.

Claim 18 (withdrawn - currently amended): A method of using a compound according to any one of claims 1-4, 1-2, 4-5 or 7 as a therapeutic agent against viral infection, said virus requiring an aspartyl protease for an obligatory life cycle event.

Claim 19 (withdrawn): The method according to claim 18, wherein said virus is HIV-1, HIV-2, or HTLV.

Claim 20 (withdrawn - currently amended): A method of ~~The use according to any one of claims 1-4, for~~ inhibiting enzymatic activity in an aspartyl protease comprising the step of contacting the aspartyl protease with a compound according to any one of claims 1-2, 4-5 or 7.

Claim 21 (withdrawn – currently amended): ~~The use~~ method according to claim 20, wherein said aspartyl protease is HIV protease.

Claim 22 (withdrawn – currently amended): A method for preventing HIV infection in a mammal comprising the step of administering to said mammal a pharmaceutically effective amount of a compound ~~pharmaceutical composition~~ according to any one of claims 1-2, 4-5 or 7 ~~claim 16 or 17.~~

Claim 23 (withdrawn – currently amended): A method for treating HIV infection in a mammal comprising the step of administering to said mammal a pharmaceutically effective amount of a compound ~~pharmaceutical composition~~ according to any one of claims 1-2, 4-5 or 7 ~~claim 16 or 17.~~

Claim 24 (withdrawn): The method according to claim 22 or 23, wherein said step of administering comprises oral administration or administration by injection.

Claims 25-27 (canceled).

Remarks

THE AMENDMENTS

Applicants have canceled claims 3 without prejudice and without waiver of their right to file for and obtain claims directed to any non-elected subject matter in divisional and continuing applications which claim priority from this application.

Applicants have amended claims 7, 12, 16, 18, 20-23 to improve their form and to recite proper claim dependencies.

Following entry of the above amendment, claims 1-2, 4-5, 7 and 11-12 are pending, claims 16-24 are withdrawn and claims 3, 6, 8-10, 13-15 and 25-27 are canceled.

None of the above amendments adds new matter.

THE RESTRICTION REQUIREMENT

Applicants maintain their traversal of the restriction requirement. Upon allowance of the Group VIII compounds, applicants will request rejoinder of the Group XI and XII process claims (claims 18-24) commensurate in scope with the allowed product claims. See MPEP § 821.04.

THE REJECTION

35 U.S.C. § 112, second paragraph

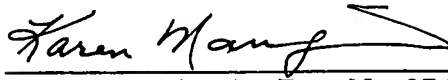
The Examiner has rejected claims 1-5, 7, 11 and 12 under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner contends that the language of claims 1 and 5 defines a "Het" group related to variable "A" but that the elected subject matter of Group VIII does not contain a "Het" group. Applicants traverse.

Applicants respectfully submit that the definition of variable "A" in claims 1 and 5 does not include "Het." Variable "A" as defined in the instant claims is selected from the group consisting of -R¹-C₁-C₆ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C₁-C₄ alkoxy, -NR²-CO-N(R²)(R²) and -CO-N(R²)(R²). As such, the only additional variables included in the definition of "A" are "R¹" and "R²," neither one of which is further defined by "Het." Accordingly, applicants request that the Examiner withdraw the rejection.

CONCLUSION

In view of the foregoing remarks and amendments, applicants request that the Examiner favorably reconsider this application and allow the amended claims pending therein. Should the Examiner feel that a telephone conference with applicants' representatives would assist the Examiner, she is invited to telephone the undersigned at any time.

Respectfully submitted,




James F. Haley, Jr. (Reg. No. 27,794)
Karen Mangasarian (Reg. No. 43,772)
Attorneys for Applicants

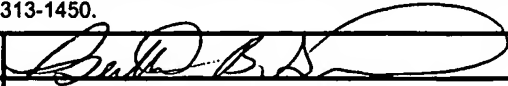
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	Filing Date	February 24, 2004	
	First Named Inventor	Roger D. Tung, et al.	
	Art Unit	1621	
	Examiner Name	Elvis O. Price	
Total Number of Pages in This Submission	18	Attorney Docket Number	VPI/92-07 CIP2A DIV3 CON

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 <input type="checkbox"/> Copy of Notice of file Missing Parts of Nonprovisional Application	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): -- Postcard
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Date	June 20, 2006	Reg. No. 43,772	

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number (Optional) VPI/92-07 CIP2A DIV3 CON	
Application Number	10/786,997	Conf. No.	9030
Filed		February 24, 2004	
For NOVEL SULFONAMIDE INHIBITORS OF ASPARTYL PROTEASE			
Art Unit	1621		Examiner Elvis O. Price

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
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☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 06-1075, Account No. 003667-0048. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration Number _____.

☒ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 43,772.

Signature
Karen Mangasarian

Typed or printed name

Date
June 20, 2006

212-596-9000

Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

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DOCKET No. VPI/92-07 CIP2A DIV3 CON
CONFIRMATION No. 9030

APPLICANT Roger D. Tung et al.

APPLICATION NO. 10/786,997

FILED February 24, 2004

RECEIPT IS HEREBY ACKNOWLEDGED OF THE
Transmittal Form with Express Mail Certification (EV674902255US);
Petition for Extension of Time Under 37 C.F.R. 1.136(a) (in duplicate); and
Amendment and Reply to Office Action.

DATED June 20, 2006

FILED IN CONNECTION WITH THE ABOVE CASE.

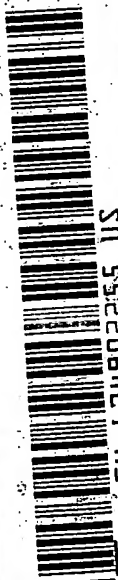
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10/786,997 Novel sulfonamide inhibitors of aspartyl protease

Application Data	Transaction History	Image File Wrapper	Continuity Data	Published Documents	Publication Dates
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06-26-2006	Abandonment
06-20-2006	Amendment - After Non-Final Rejection
06-20-2006	Claims
06-20-2006	Applicant Arguments/Remarks Made in an Amendment
06-20-2006	Extension of Time
06-20-2006	Transmittal to TC
12-20-2005	Non-Final Rejection
12-20-2005	List of References cited by applicant and considered by examiner
12-20-2005	Examiner Interview Summary Record (PTC 413)
12-20-2005	Index of Claims
12-20-2005	Search information including classification databases and other search related notes
12-20-2005	Bibliographic Data Sheet
10-25-2005	Examiner's search strategy and results
01-12-2005	Information Disclosure Statement (IDS) Fi

12-21-2004	<u>Claims Worksheet (PTO-2022)</u>
12-21-2004	<u>Fee Worksheet (PTO-875)</u>
12-21-2004	<u>Fee Worksheet (PTO-875)</u>
12-21-2004	<u>Amendment - After Non-Final Rejection</u>
12-21-2004	<u>Claims</u>
12-21-2004	<u>Applicant Arguments/Remarks Made in an Amendment</u>
12-21-2004	<u>Extension of Time</u>
12-21-2004	<u>Miscellaneous Incoming Letter</u>
09-22-2004	<u>Requirement for Restriction/Election</u>
09-22-2004	<u>Index of Claims</u>
02-24-2004	<u>Transmittal letter</u>
02-24-2004	<u>Specification</u>
02-24-2004	<u>Claims</u>
02-24-2004	<u>Abstract</u>
02-24-2004	<u>Drawings</u>
02-24-2004	<u>Oath or Declaration filed</u>
02-24-2004	<u>Preliminary Amendment</u>
02-24-2004	<u>Specification</u>
02-24-2004	<u>Applicant Arguments/Remarks Made in an Amendment</u>
02-24-2004	<u>Application Data Sheet</u>
02-24-2004	<u>Claims Worksheet (PTO-2022)</u>
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PATENTS

Attorney Docket No. VPI92-07CIP2ADIV3CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Examiner : Elvis O. Price
Group Art Unit : 1621
Applicants : Roger D. Tung, et al.
Application No. : 10/786,997 Confirmation No. : 9030
Filed : February 24, 2004
For : NOVEL SULFONAMIDE INHIBITORS OF
ASPARTYL PROTEASE

New York, New York 10020
June 20, 2006

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

AMENDMENT AND REPLY TO OFFICE ACTION

Sir:

This is in response to the December 20, 2005 Office Action in the above-identified application. Applicants submit concurrently herewith a Petition under 37 C.F.R. § 1.17(a)(3) to extend the time for replying for a period of three months up to and including June 20, 2006.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

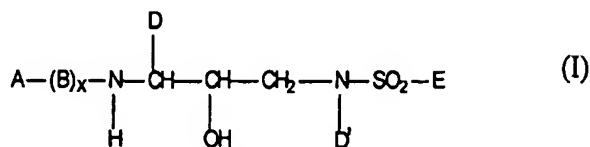
Remarks begin on page 12 of this paper.

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (previously presented): A compound of formula I:



wherein:

A is selected from the group consisting of $-\text{R}^1-\text{C}_1-\text{C}_6$ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C_1-C_4 alkoxy, $-\text{NR}^2-\text{CO}-\text{N}(\text{R}^2)(\text{R}^2)$ and $-\text{CO}-\text{N}(\text{R}^2)(\text{R}^2)$;

each R^1 is independently selected from the group consisting of $-\text{C}(\text{O})-$, $-\text{S}(\text{O})_2-$, $-\text{C}(\text{O})-\text{C}(\text{O})-$, $-\text{O}-\text{C}(\text{O})-$, $-\text{O}-\text{S}(\text{O})_2-$, $-\text{NR}^2-\text{S}(\text{O})_2-$, $-\text{NR}^2-\text{C}(\text{O})-$ and $-\text{NR}^2-\text{C}(\text{O})-\text{C}(\text{O})-$;

each Het is independently selected from the group consisting of C_3-C_7 cycloalkyl; C_5-C_7 cycloalkenyl; C_6-C_{10} aryl; and 5-7 membered saturated or unsaturated heterocycle, containing one heteroatom selected from N, $\text{N}(\text{R}^2)$, O, S and $\text{S}(\text{O})_n$, wherein said heterocycle may optionally be benzofused; and wherein any member of said Het

may be optionally substituted with one or more substituents selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)(R^2)$, $-R^2-OH$, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)(R^2)$, $-S(O)_2-N(R^2)(R^2)$, $-N(R^2)-C(O)-R_2$, $-C(O)-R^2$, $-S(O)_n-R^2$, $-OCF_3$, $-S(O)_n-Ar$, methylenedioxy, $-N(R^2)-S(O)_2(R^2)$, halo, $-CF_3$, $-NO_2$, Ar and $-O-Ar$;

each R^2 is independently selected from the group consisting of H and C_1 - C_3 alkyl optionally substituted with Ar; with the proviso that when R^2 is C_1 - C_3 alkyl substituted with Ar, said Ar may not be substituted with an Ar-containing moiety;

B, when present, is $-N(R^2)-C(R^3)(R^3)-C(O)-$;

x is 0 or 1;

each R^3 is independently selected from the group consisting of H, Het, C_1 - C_6 alkyl, C_2 - C_6 alkenyl, C_3 - C_6 cycloalkyl and C_5 - C_6 cycloalkenyl, wherein any member of said R^3 , except H, may be optionally substituted with one or more substituents selected from the group consisting of $-OR^2$, $-C(O)-NH-R^2$, $-S(O)_n-N(R^2)(R^2)$, Het, $-CN$, $-SR^2$, $-CO_2R^2$, $NR^2-C(O)-R^2$;

each n is independently 1 or 2;

D and D' are independently selected from the group consisting of Ar; C_1 - C_4 alkyl, which may be optionally substituted with one or more groups selected from C_3 - C_6 cycloalkyl, $-OR_2$, $-R^3$, $-O-Ar$ and Ar; C_2 - C_4 alkenyl, which may be optionally substituted with one or more groups selected from the group consisting of C_3 - C_6 cycloalkyl, $-OR^2$, $-R^3$, $-O-Ar$ and Ar; C_3 - C_6 cycloalkyl, which may be optionally substituted with or fused with Ar; and C_5 - C_6 cycloalkenyl, which may be optionally

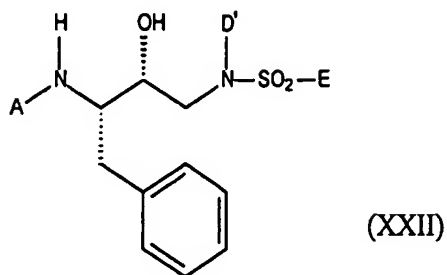
substituted with or fused with Ar;

each Ar is independently selected from the group consisting of phenyl; 3-6 membered carbocyclic ring, wherein said carbocyclic ring may be saturated or unsaturated and optionally substituted with one or more groups selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)(R^2)$, $-N(R^2)-C(O)-R^2$, C_1-C_3 alkyl substituted with -OH and optionally substituted with Ar, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)(R^2)$, halo and $-CF_3$;

E is selected from the group consisting of Het; O-Het; Het-Het; $-OR^3$; $-NR^2R^3$; C_1-C_6 alkyl, which may be optionally substituted with one or more groups selected from the group consisting of R^4 and Het; C_2-C_6 alkenyl, which may be optionally substituted with one or more groups selected from the group consisting of R^4 and Het; C_3-C_6 saturated carbocycle, which may optionally be substituted with one or more groups selected from the group consisting of R^4 and Het; and C_5-C_6 unsaturated carbocycle, which may optionally be substituted with one or more groups selected from the group consisting of R^4 and Het; and

each R^4 is independently selected from the group consisting of $-OR^2$, $-C(O)-NHR^2$, $-S(O)_2-NHR^2$, halo, $-NR^2-C(O)-R^2$ and $-CN$.

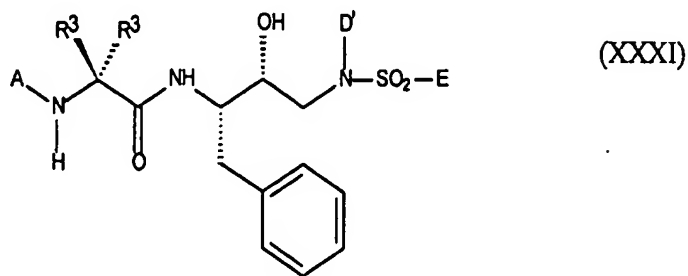
Claim 2 (original): The compound according to claim 1, characterized in that said compound has the structure of formula XXII:



and A, D' and E are defined as in claim 1.

Claim 3 (canceled).

Claim 4 (original): The compound according to claim 1, characterized in that said compound has the structure of formula XXXI:



and A, R³, D' and E are defined as in claim 1.

Claim 5 (previously presented): A compound of formula I, wherein:

A is selected from the group consisting of $-R^1-C_1-C_6$ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C_1-C_4 alkoxy;

each R^1 is independently selected from the group consisting of $-C(O)-$, $-S(O)_2-$, $-C(O)-C(O)-$, $-O-CO-$, $-O-S(O)_2-$ and $-NR^2-S(O)_2-$;

each Het is independently selected from the group consisting of C_3-C_7 cycloalkyl; C_5-C_7 cycloalkenyl; C_6-C_{10} aryl; and 5-7 membered saturated or unsaturated heterocycle, containing one heteroatom selected from N, O and S, which may optionally be benzofused; wherein any member of said Het may be optionally substituted with one or more substituents selected from the group consisting of oxo, $-OR^2$, $-R^2$, $-N(R^2)_2$, $-R^2-OH$, $-CN$, $-CO_2R^2$, $-C(O)-N(R^2)_2$ and $-S(O)_2-N(R^2)_2$;

each R^2 is independently selected from the group consisting of H and C_1-C_3 alkyl;

B, when present, is $-NH-CH(R^3)-C(O)-$;

x is 0 or 1;

R^3 is selected from the group consisting of Het, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_3-C_6 cycloalkyl and C_5-C_6 cycloalkenyl, wherein any member of said R^3 may be optionally substituted with one or more substituents selected from the group consisting of $-OR^2$, $-C(O)-NH-R^2$, $-S(O)_n-N(R^2)_2$, Het and $-CN$;

n is 1 or 2;

D and D' are independently selected from the group consisting of Ar; C₁-C₄ alkyl, which may be optionally substituted with C₃-C₆ cycloalkyl or Ar; C₂-C₄ alkenyl, which may be optionally substituted with C₃-C₆ cycloalkyl or Ar; C₃-C₆ cycloalkyl, which may be optionally substituted or fused with Ar; and C₅-C₆ cycloalkenyl, which may be optionally substituted or fused with Ar;

Ar is selected from the group consisting of phenyl; 3-6 membered carbocyclic ring wherein said carbocyclic ring may be saturated or unsaturated and optionally substituted with one or more groups selected from the group consisting of oxo, -OR², -R², -N(R²)₂, -N(R²)-C(O)R², -R²-OH, -CN, -CO₂R², -C(O)-N(R²)₂, halo and -CF₃;

E is selected from the group consisting of Het; -O-R³; -NR²R⁵; C₁-C₆ alkyl, which may be optionally substituted with one or more R⁴ or Het; C₂-C₆ alkenyl, which may be optionally substituted with one or more R⁴ or Het; C₃-C₆ saturated carbocycle, which may optionally be substituted with one or more R⁴ or Het; and C₅-C₆ unsaturated carbocycle, which may optionally be substituted with one or more R⁴ or Het;

each R⁴ is independently selected from the group consisting of -OR², -C(O)-NHR², -S(O)₂-NHR², halo and -CN; and

each R⁵ is independently selected from the group consisting of H and R³.

Claim 6 (canceled).

Claim 7 (currently amended): The compound according to claim 1, wherein:

R³ is selected from the group consisting of C₁-C₆ alkyl, C₂-C₆ alkenyl, C₅-

C₆ cycloalkyl, C₅-C₆ cycloalkenyl and a 5-6 membered saturated or unsaturated heterocycle, wherein any member of said R³ may optionally be substituted with one or more substituents selected from the group consisting of -OR², -C(O)-NH-R², -S(O)_nN(R²)(R²), Het, -CN, -SR², -C(O)₂R², NR²-C(O)-R²; and

D' is selected from the group consisting of C₁-C₃ alkyl and C₃ alkenyl, wherein said alkyl or alkenyl may optionally be substituted with one or more groups selected from the group consisting of C₃-C₆ cycloalkyl, -OR², -O-Ar and Ar.

Claims 8-10 (canceled).

Claim 11 (original): The compound according to claim 1, wherein said compound has a molecular weight less than or equal to about 700 g/mol.

Claim 12 (currently amended): A The compound according to claim 11, wherein said compound has a molecular weight less than or equal to about 600 g/mol.

Claims 13-15 (canceled).

Claim 16 (withdrawn – currently amended): A pharmaceutical composition effective against viral infection comprising a pharmaceutically effective amount of a compound according to any one of claims 1-2 or 4 and a pharmaceutically acceptable carrier, adjuvant or vehicle.

Claim 17 (withdrawn): The pharmaceutical composition according to claim 16, further comprising an additional anti-viral agent.

Claim 18 (withdrawn - currently amended): A method of using a compound according to any one of claims 1-4, 1-2, 4-5 or 7 as a therapeutic agent against viral infection, said virus requiring an aspartyl protease for an obligatory life cycle event.

Claim 19 (withdrawn): The method according to claim 18, wherein said virus is HIV-1, HIV-2, or HTLV.

Claim 20 (withdrawn - currently amended): A method of ~~The use according to any one of claims 1-4, for~~ inhibiting enzymatic activity in an aspartyl protease comprising the step of contacting the aspartyl protease with a compound according to any one of claims 1-2, 4-5 or 7.

Claim 21 (withdrawn – currently amended): ~~The use~~ method according to claim 20, wherein said aspartyl protease is HIV protease.

Claim 22 (withdrawn – currently amended): A method for preventing HIV infection in a mammal comprising the step of administering to said mammal a pharmaceutically effective amount of a compound ~~pharmaceutical composition~~ according to any one of claims 1-2, 4-5 or 7 ~~claim 16 or 17.~~

Claim 23 (withdrawn – currently amended): A method for treating HIV infection in a mammal comprising the step of administering to said mammal a pharmaceutically effective amount of a compound ~~pharmaceutical composition~~ according to any one of claims 1-2, 4-5 or 7 ~~claim 16 or 17.~~

Claim 24 (withdrawn): The method according to claim 22 or 23, wherein said step of administering comprises oral administration or administration by injection.

Claims 25-27 (canceled).

Remarks

THE AMENDMENTS

Applicants have canceled claims 3 without prejudice and without waiver of their right to file for and obtain claims directed to any non-elected subject matter in divisional and continuing applications which claim priority from this application.

Applicants have amended claims 7, 12, 16, 18, 20-23 to improve their form and to recite proper claim dependencies.

Following entry of the above amendment, claims 1-2, 4-5, 7 and 11-12 are pending, claims 16-24 are withdrawn and claims 3, 6, 8-10, 13-15 and 25-27 are canceled.

None of the above amendments adds new matter.

THE RESTRICTION REQUIREMENT

Applicants maintain their traversal of the restriction requirement. Upon allowance of the Group VIII compounds, applicants will request rejoinder of the Group XI and XII process claims (claims 18-24) commensurate in scope with the allowed product claims. See MPEP § 821.04.

THE REJECTION

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-5, 7, 11 and 12 under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner contends that the language of claims 1 and 5 defines a "Het" group related to variable "A" but that the elected subject matter of Group VIII does not contain a "Het" group. Applicants traverse.

Applicants respectfully submit that the definition of variable "A" in claims 1 and 5 does not include "Het." Variable "A" as defined in the instant claims is selected from the group consisting of $-R^1-C_1-C_6$ alkyl, which may be optionally substituted with one or more groups selected from the group consisting of hydroxy, C_1-C_4 alkoxy, $-NR^2-CO-N(R^2)(R^2)$ and $-CO-N(R^2)(R^2)$. As such, the only additional variables included in the definition of "A" are " R^1 " and " R^2 ," neither one of which is further defined by "Het." Accordingly, applicants request that the Examiner withdraw the rejection.

CONCLUSION

In view of the foregoing remarks and amendments, applicants request that the Examiner favorably reconsider this application and allow the amended claims pending therein. Should the Examiner feel that a telephone conference with applicants' representatives would assist the Examiner, she is invited to telephone the undersigned at any time.

Respectfully submitted,



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PTO/SB/22 (12-04)

Approved for use through 7/31/2006. OMB 0851-0031

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

FY 2006

(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)

Docket Number (Optional)

VPI/92-07 CIP2A DIV3 CON

Application Number 10786,997

Conf. No. 9030

Filed

February 24, 2004

For **NOVEL SULFONAMIDE INHIBITORS OF ASPARTYL PROTEASE**

Art Unit 1621

Examiner Elvis O. Price

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ <u>\$1,020.00</u>
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ _____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 06-1075, Account No. 003667-0048. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☐ attorney or agent of record. Registration Number _____.

☒ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 43,772.



Signature

Karen Mangasarian

Typed or printed name

June 20, 2006

Date

212-596-9000

Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(e). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Application Number

10/786,997 Conf. No. 9030

Filing Date

February 24, 2004

First Named Inventor

Roger D. Tung, et al.

Art Unit

1621

Examiner Name

Elvis O. Price

Attorney Docket Number

VPI/92-07 CIP2A DIV3 CON

ENCLOSURES (Check all that apply)☐ Fee Transmittal Form☐ Fee Attached☒ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☒ Extension of Time Request☐ Express Abandonment Request☐ Information Disclosure Statement☐ Certified Copy of Priority Document(s)☐ Response to Missing Parts/
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Fish & Neave IP Group
Ropes & Gray LLP

Customer No. 1473

Signature



Printed name

Karen Mangasarian

Date

June 20, 2006

Reg. No.

43,772

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